1000-1420 PCI's annually with operators using a default femoral (F) access for PCI then progressing to a R approach. Data on patient demographics, procedure details, fluoroscopy time and radiation doses and outcomes were collected from internal and national databases.
Results: 6575 patients underwent PCI over a 5 yr period. In 5yrs, R access increased from 31.4% to 90%(p<0.0001). The access change from was seen amongst all operators and patient groups. The x-over rate from R to F access to finish the PCI was 1.5% compared to a F to R x-over of 6.2%(p=ns). There was an increase in fluoroscopy (R)1097.8 vs (F)851.8 sec (p=0.001) and radiation dose (R)63.9vs(F)57.3cGycm2(p=0.01) during yr1 when operators went from 32 to 67% R approach. There were no differences in fluoroscopy time (R)919.9vs.(F)896.3sec,p=ns) and radiation dose(R)62.7vs(F)62.7 cGycm2,p=ns in yr2+3.In yr4+5 when R use was 90% of cases; fluoroscopy time (R)919.4vs(F)1124.4sec, P=0.007 and radiation dose(R)70.4vs(F)86.4cGycm2,P=0.01 decreased. Over 5yrs, vascular complications and major bleeding were higher in the F group (2.32%vs1.00%, p<0.001; 1.12% vs 0.10%, p<0.0001) while length of stay was shorter in the R group 0.75 vs 1.07 days, p<0.0001).
Conclusions: Adoption of the R approach in centres performing PCI predominantly via the F route is feasible within 5yrs and translates into both clinical and economic benefits with reductions in hospital stay and vascular/bleeding complications. There is however a 'learning curve' which results in increased fluoroscopy time and radiation doses in the initial phases, which is reversed once the radial approach is used in >60% of PCI cases.

TCT-28

Is the rate of femoral access site complications increased in the hands of "radialists"?

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Background: Transradial approach (TRA) for coronary angiography and interventions was shown to be associated with a striking reduction in the rate of vascular access site complications (VASC) as compared to transfemoral approach (TFA). As a result, the prevalence of TRA is increasing worldwide, with a growing proportion of physicians who select TRA as their preferred approach in the vast majority of cases (so called "radialists"). A possible drawback of this behaviour could be the loss of expertise in TFA, potentially leading to an increased rate of VASC when TFA is needed due to clinical (e.g. cardiogenic shock) or technical reasons (e.g. need for large guiding catheters).
Methods: We designed a prospective, single center, 3-years registry aimed to investigate whether high-volume TRA operators (HTRAop; >75% TRA) experience an increased rate of femoral VASC as compared to lower-volume TRA operators (LTRAop; <75% TRA). All femoral VASC requiring interventions or prolonging hospital stay were recorded.
Results: Between May 2009 and May 2012 2749 procedures, of which 1255 percutaneous coronary interventions (PCI), were performed at our Institution by 4 main operators. HTRAop performed 1466 procedures, whereas LTRAop performed 1283 procedures. The rate of TRA was 78.6% (range 76.7-80.6) in HTRAop and 61.7% (61.3-62.2) in LTRAop (p<0.001). The rate of PCI was 47.9% in HTRAop vs 43.1% in LTRAop (p<0.05). The majority of procedures were performed with 6F sheaths; 4 procedures were performed with 5F and 150 with 7F sheaths. Vascular closure devices were only used in 25 patients (0.91%). We observed 12 femoral VASC: 8 pseudoaneurysms (6 of which treated by echo-guided compression, the remaining by surgery), 3 cases of limb ischemia, treated by surgery, and 1 case of femoral vein thrombosis. In TFA procedures, the rate of femoral VASC was not different between HTRAop and LTRAop (0.96% vs 1.84%; p=0.38). Overall, less femoral VASC were observed in HTRAop as compared to LTRAop (0.20% vs 0.70%; p<0.05).
Conclusions: Our data do not support the concern that high-volume TRA operators could experience a higher rate of femoral VASC when performing TFA. A higher TRA rate is actually associated with less femoral VASC.

TCT-29

Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes: results of the Zwolle Myocardial Infarction Study Group

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Background: Trials have suggested that radial access for percutaneous coronary intervention (PCI) reduces vascular complications and bleeding compared with femoral access. Aim of this study was to assess the efficacy and safety of radial access versus femoral access in patients (pts) with acute coronary syndromes (ACS) who underwent coronary angiography with possible intervention.
Methods: This is a single-centre, large, prospective observational registration of all STEMI and NSTEMI pts who underwent coronary angiography and/or (primary) PCI in the period January 2010–December 2011. Primary endpoint was in-hospital non CABG-related major and minor bleeding. All safety- and clinical parameters, including bleeding were performed by 2 independent investigators.
Results: Of the 2295 ACS patients, 56.2% were diagnosed with STEMI and 43.8% with a NSTEMI on admission. Coronary angiography was performed in 2042/2295 (89%) and in 334/2042 pts (16%) by radial access. PCI was performed in 1506/2033 (74.1%) of the pts. No differences in baseline or angiographic characteristics were present between radial vs femoral access patients except for diagnosis of STEMI: 48.5% vs 61.0%, p<0.001, IABP use: 0.9% vs 7.1%, p<0.001, and Killip class≥2: 6.6% vs 12.8%, p=0.001). The primary endpoint occurred less often in the radial group as compared to the femoral group (0.9% vs 3.4%, p=0.014), especially in the subgroup of pts with a moderate, high or very high CRUSADE bleeding score (0.0% vs 7.5%, p=0.012). 30-day mortality was significantly lower in the radial group as compared to the femoral group (1.7% vs 4.8%, p=0.014). However, radial access was neither an independent predictor for the primary endpoint (HR 0.417; 95% CI, 0.125–1.316, p=0.136), as for 30-day mortality (HR 0.50; 95% CI, 0.182–1.415, p=0.195).
Conclusions: Although radial access significantly reduced in-hospital non CABG-related major and minor bleeding and 30-day mortality as compared to femoral access, the difference was no longer significant after multivariate correction for differences in baseline and angiographic characteristics between the groups.

TCT-30

Clinical Outcomes Following Radial Versus Femoral Artery Access In Primary Or Rescue Percutaneous Coronary Intervention In Scotland: Retrospective Cohort Study Of 4534 Patients

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Background: Bleeding during emergency percutaneous coronary intervention (PCI) predicts reduced survival. Radial artery access potentially reduces the risk of bleeding. We aimed to assess short-term and medium-term outcomes following radial and femoral artery access for primary or rescue percutaneous coronary intervention (PCI).
Methods: A retrospective cohort study in Scotland, UK. All 4534 patients who had primary or rescue PCI in Scotland between April 2000 and March 2009 were identified using the Scottish Coronary Revascularisation Register. The outcome measures were procedural success; peri-procedural complications; 30-day and 1-year mortality, myocardial infarction or stroke and long-term mortality.
Results: Use of the radial approach increased from no cases in 2000 to 924 (80.5%) in 2009 (p<0.001). Patients in whom the radial approach was used were more likely to be male (p=0.041) and to have multiple comorbidities (p<0.001), including hypertension (p<0.001) and left ventricular dysfunction (p<0.001). They were less likely to have renal impairment (p=0.017), multi-vessel coronary disease (p=0.001) and cardiogenic shock (p<0.001). In multivariable analyses, use of radial artery access was associated with greater procedural success (adjusted OR 1.89, 95% CI 1.26 - 2.82, p=0.002) and a lower risk of any complications (adjusted OR 0.67, 95% CI 0.51 - 0.87, p=0.001) or access site bleeding complications (adjusted OR 0.21, 0.08 - 0.56, p=0.002), as well as a lower risk of myocardial infarction (adjusted OR 0.66, 95% CI 0.51-0.87, p=0.003) or death within 30 days (adjusted OR 0.51, 95% CI 0.04 - 0.52, p<0.001). The differences in myocardial infarction and death remained significant up to 9 years of follow-up.
Conclusions: Compared with femoral artery access, use of the radial artery for primary or rescue PCI is associated with improved clinical outcomes.

TCT-31

Clinical Benefit of Radial Versus Femoral Approach in Percutaneous Coronary Intervention with Intra-Aortic Balloon Pump Support

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Background: Peri-procedural bleeding complications have been associated with a worse outcome in patients undergoing percutaneous coronary intervention (PCI), especially in the context of acute coronary syndromes (ACSs). This study aims to assess if the selection of transradial approach to perform PCI still represents an advantage in terms of bleeding reduction also in patients needing intra-aortic balloon pump (IABP) support.
Methods: We retrospectively analyzed 241 consecutive patients receiving IABP support during PCI in four independent high-volume centers. Patients were further divided in two groups: 116 patients receiving double femoral access (FF) and 125 receiving both radial and femoral (RF) approaches. Primary end-points were assessment of in-hospital Net Adverse Clinical Events (NACE, composite of post-procedural bleeding, cardiac death, myocardial infarction, target lesion revascularization or stroke) and bleeding (defined according to ARC classification) rates.
Results: Median patient age was 71 [1st-3rd quartile 61-79] years and diagnosis at admission was ACS in 91% of patients, including acute ST elevation myocardial infarction in 73%. High-risk patient profile included Killip class 3-4 presentation in 78%, mean systolic arterial pressure 90 [70-100] mmHg, mean left ventricle ejection fraction 30% [25-40] and multivessel coronary artery disease in 70% involving left main trunk in 26% of cases. Cumulative 30-day NACE rate was 54% (130), while a bleeding occured in 29% of patients. NACEs were more frequent in the FF group when compared to the RF

group (67% vs. 41%, p<0.01). In particular this difference stemmed from an increase of access site-related bleeding (21% vs. 7%, p<0.01) and cardiac death (41% vs. 25%, p<0.01) in the FF group. The adjusted multivariable regression analysis confirmed radial approach as independent outcome predictor (OR 0.53 CI 95% 0.29-0.96, p=0.037).
Conclusions: Transradial approach use for PCI requiring IABP support positively impacts periprocedural outcome by means of a significant access-site-related bleeding and cardiac death prevention. Thus, its use seems strongly recommended in patients at increased risk of bleeding, such as those admitted for an ACS.

TCT-32

Neurological complications following PCI - incidence and trends during a period of transition from femoral to radial access. Observational data from the british cardiovascular intervention society PCI database

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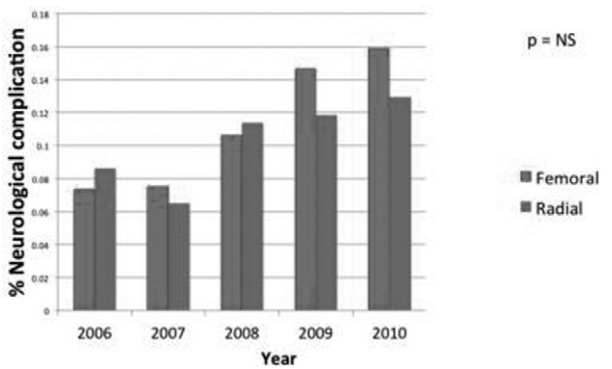
Background: There has been a significant increase in use of transradial access (TRA) for PCI in the UK. Early on in the TRA learning curve, procedures are associated with more catheter exchanges, longer screening times and with more contrast use. These factors are all associated with increased risk of periprocedural neurological complications (NC). Using the British Cardiovascular Intervention Society PCI database we assessed changes in NC through a period of transition during which radial access became the dominant access for PCI.
Methods: This study includes data collected by the British Cardiovascular Intervention Society under the auspices of the Central Cardiac Audit Database. We performed a retrospective analysis of the BCIS database between January 2006 and December 2010. The data was split into 2 cohorts based on access site: either radial or femoral (mixed access site use and other access sites were excluded from the analysis). A NC was defined as a periprocedural TIA, ischemic stroke or hemorrhagic stroke.
Results: Between 2006 and 2010 a total of 348,092 procedures were recorded exclusively using either transradial (TRA) or tansfemoral (TFA) access. Over 5 years, the use of TRA for PCI increased from 17.1% to 50.8% of procedures. There was no difference in the incidence of NC during this period. Following multivariate analysis of the whole 5 year cohort, no difference in NC was observed between TRA and TFA (HR 1.005 CI 0.81-1.248: p=0.96).



Conclusions: These results are reassuring and suggest that a switch from TFA to TRA is not associated with any increased risk of periprocedural neurological complications.

Bioresorbable Vascular Scaffolds

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TCT-33

Intracoronary Optical Coherence Tomography and Histology of Overlapping Everolimus-Eluting Bioresorbable Vascular Scaffolds in a Porcine Coronary Artery Model: The Potential Implications for Clinical Practice

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Background: The everolimus-eluting Bioresorbable Vascular Scaffold (Absorb) is a novel approach to treating coronary lesions. A persistent inflammatory response, fibrin deposition and delayed endothelialisation have been reported with overlapping first-generation drug eluting stents. We report optical coherence tomography and histological findings in a porcine coronary artery model after implantation of overlapping Absorb or second-generation everolimus-eluting metallic platform stents (XIENCE V [XV]).
Methods: 41 overlapping Absorb and overlapping XV devices (3.0×12 mm) were implanted in the main coronary arteries of 17 non-atherosclerotic pigs with a balloon artery ratio of 1.1:1 (10% over-stretch). Implanted coronary arteries were evaluated by OCT at 28 (Absorb: n=11, XV: n= 7) and 90 days (Absorb: n=11, XV: n= 8), with immediate histological evaluation following euthanasia at the same time points. One animal from each time point was evaluated with scanning electron microscopy alone.
Results: 1407 cross-sections were analysed by OCT and 148 cross-sections analysed histologically. At 28 days in the overlap, OCT analyses indicated 80.1% of Absorb struts and 99.4% of XV struts to be covered (p<0.0001), corresponding to histological observations of struts with cellular coverage of 75.4% and 99.6% respectively (p<0.001). Uncovered struts were almost exclusively related to the presence of 'stacked' Absorb struts, i.e. with a direct overlay configuration. At 90 days overlapping Absorb and overlapping XV struts demonstrated >99% strut coverage by OCT and histology, with no evidence of a significant inflammatory process, and comparable % volume obstructions.
Conclusions: In porcine coronary arteries implanted with overlapping Absorb, strut coverage is dependent on the overlay configuration of Absorb struts at 28 days and not at 90 days. The potential clinical implications of increased strut thickness in the management of long lesions & coronary bifurcations may have important clinical (e.g. duration of antiplatelet therapy) and design considerations (e.g. longer devices & the requirement of dedicated bifurcation devices to avoid overlapping the device) for current and future devices with bioresorbable platforms.

TCT-34

ABSORB EXTEND: An Interim Report on the 12-month Clinical Outcomes from the First 250 Patients Enrolled

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Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (BVS) System (Abbott Vascular, Santa Clara, CA) has been previously established in 131 patients from Cohort A and Cohort B of the First-in-Man ABSORB trial. Results out to 2 years have been presented in 101 patients from the ABSORB Cohort B trial. At 12 months, the MACE rate was 6.9%, with no scaffold thrombosis reported, which was sustained out to 2 years with a MACE rate of 9.0%. Following this trial, ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb BVS.
Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that is planning to enroll up to 1,000 subjects at up to 100 sites. Included are patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.3 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, is permitted.
Results: Interim 12-month data in the first 250 patients enrolled in ABSORB EXTEND will be available for the first time in October 2012 and will provide additional data on the